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SEP 07 2007

CLAIM AMENDMENTS

The following amendment to Claim 19 is proposed:

Claim 19: An electronic stethoscope with expanded program execution and communications capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements comprising

Central processing unit,

Nonvolatile digital memory means selected from a group consisting of Flash memory, EEPROM, and magnetic media,

One or more software programs, executable by said central processing unit, which expand the functions executed by said stethoscope,

Said functions comprising medical measurement, information processing and communications functions,

Digital communications means,

Wherein said software programs are transferred via said digital communications means, stored in said nonvolatile digital memory means, and executed by said central processing unit.

The following amendment to Claim 35 is proposed:

Claim 35: An electronic stethoscope with expanded patient information acquisition capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising;

Central processing unit,

Battery power supply,

Physiological measurement means for detecting and reproducing body sounds,

video input means to record still or moving images of a patient,

Wherein said central processing unit and said battery power supply provide control and electrical power respectively to all of said physiological and video input means,

and said housing provides a unified portable platform for housing, carrying and operating said elements.

Claims to be withdrawn: Claims 20, 21 and 34.

In response to Examiner Request, the following minor amendments are proposed for claims 22-30 and claim 36 to include the word "said" as required and requested by Examiner:

22. The electronic stethoscope as in Claim 19 wherein said digital memory means is physically removable from electronic stethoscope housing.

23. The electronic stethoscope as in Claim 19 wherein said digital communications means is a wired cable.

24. The electronic stethoscope as in Claim 19 wherein said digital communications means is an infrared optical communications link.

25. The electronic stethoscope as in Claim 19 wherein said digital communications means is a wireless communications link.

26. The electronic stethoscope as in Claim 19 wherein said digital communications means is a wireless communications means physically removable from said electronic stethoscope housing.

27. The electronic stethoscope as in Claim 19 wherein said digital communications means uses an 802.11 communications protocol.

28. The electronic stethoscope as in Claim 19 wherein said digital communications means uses an Internet protocol selected from the group TCP/IP, FTP, PPP communications protocols.

29. The electronic stethoscope as in Claim 19 wherein said one or more software programs are medical information software programs selected from the group drug dosage database access software, drug interaction database access software, medical research database access software.

30. The electronic stethoscope as in Claim 29 further comprising a barcode reader operatively connected to said central processing unit such that database reading and writing can be effected by barcode scanner input.

31. The electronic stethoscope as in Claim 19 wherein said software includes algorithms for the processing of auscultation sounds.

Claim 36: An electronic stethoscope with expanded audio capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising;

Central processing unit,

Battery power supply,

First audio input means for detecting body sounds,

Second audio input means for detecting voice sounds,

Digital memory means for recording said body sounds and voice sounds,

Headphones for audio reproduction integrated into portable housing,

Wherein said central processing unit, said battery power supply, and said digital memory means provide control, electrical power, and storage capability, respectively, to both said first and said second audio input means, said headphones provide audio output for both first and second input means, and said housing provides a unified portable platform for housing and carrying said elements.

REASONS FOR ALLOWANCE

Reasons for Allowance of amended Claim 19 in light of Bredesen or other prior art:

Claim 19 recites a stethoscope whose functions can be expanded by transferring software via a digital communications means to be stored and executed in the stethoscope. The closest prior art, Bredesen (US 5,010,889) individually or in combination with other prior art (a) does not recite features recited in the claimed invention and (b) there is no suggestion or motivation for the claimed invention in the prior art references taken individually or in combination.

Considering the specific elements of amended Claim 19 that differ from the Bredesen patent, the claim recites:

> **Nonvolatile digital memory means selected from a group consisting of Flash memory, EEPROM, and magnetic media,**

Bredesen discloses 2 types of memory – (i) volatile random access memory (RAM) which **loses its data** when the rechargeable batteries discharge and (ii) non-volatile memory that **cannot be written to with new software**, as claimed in the present invention. The memory claimed in the present invention is **both rewriteable and non-volatile** and therefore provides for the transfer and **storage** of software. This is not possible using Bredesen's memory and is not suggested or motivated in the prior art individually or in combination.

> **One or more software programs, executable by said central processing unit, which expand the functions executed by said stethoscope,**
>
> **Said functions comprising medical measurement, information processing and communications functions,**

The present invention recites a means for expanding stethoscope functions by means of transferring software. Bredesen makes no suggestion that (i) **software** can be **transferred** to his stethoscope invention or (ii) that there is any suggestion or motivation to **expand the functions** of the stethoscope by any means whatsoever. There is also no suggestion motivated by any other prior art to expand functions via software transfer.

> **Wherein said software programs are transferred via said digital communications means, stored in said nonvolatile digital memory means, and executed by said central processing unit.**

Bredesen and other prior art, individually or in combination, does not (i) disclose the transfer of software programs via a digital communications means (ii) disclose memory that has the properties to, or connected such that it can, provide for the non-volatile storage of software, or (iii) suggest the expansion of functions of a stethoscope as claimed in the present invention.

The difference between Bredesen and the present invention as claimed is substantial. Whereas the present invention recites software transfer, Bredesen discloses heart sounds waveform transfer. Whereas the present invention recites non-volatile memory to store transferred software, Bredesen discloses only volatile memory for heart sound memory and volatile memory is entirely unsuited to software storage in a portable device such as a stethoscope. Whereas the present invention recites expansion of functions, Bredesen individually or combined with other prior art makes no suggestion or motivation for expanding the functions of a stethoscope. There are simply too many inventive steps required between Bredesen and the present invention.

Given that there is no suggestion or motivation for the transfer of software or the expansion of functions for a stethoscope, it is therefore clear that the only way to invent the present invention from the prior art is through a hindsight reconstruction of Applicant's claims.

(Applicant has previously communicated with Examiner via meeting, telephone and fax highlighting further differences between Bredesen and the present invention with regards to software, memory, data port design and hardware design, demonstrated with physical embodiments of the present invention. This information is not repeated here, but provides further argument in support of allowance.)

Reasons for Allowance of Claim 19 in light of KSR v. Teleflex.

In light of KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), the Court has argued for consideration of "common sense" and other considerations beyond a literal reading of the prior art in order to determine obviousness. The question is therefore whether the present invention is obvious given both knowledge and common sense on the part of those skilled in the art, even if the prior art does not teach, suggest, or motivate the claimed invention.

The claimed invention concerns the **expansion of the functions of a stethoscope via the transfer of software via a data communications means**, said software being stored in a non-volatile memory. In KSR, the Court stated that "Often it will be necessary ... to look to the effects of demands known to the design community or present in the marketplace and to the background knowledge possessed by a person having ordinary skill." It is therefore pertinent to consider whether one with ordinary skill, using common sense, might modify Bredesen and other prior art to invent a stethoscope with expanded functions achieved by downloading software.

Considering first the "marketplace" and "demands known to the design community" aspect of KSR, consider that the priority date for the present invention is October 5th 1998. There have therefore been nine years of marketplace activity following the priority date. In this time, virtually every stethoscope manufacturer has released multiple generations of electronic stethoscopes. To date, to Applicant's knowledge as a participant in this marketplace, Applicant is the only inventor to have released a stethoscope with software transfer and storage capability as claimed in the present invention. The closest prior art, the Bredesen

patent, was issued in April 1991, and the Bredesen invention was marketed from about 1994 until about 2000. The Bredesen device, essentially the Bredesen invention reduced to practice, did not possess software transfer capability. Other inventors have had 16 years to apply "common sense" to his invention and device, and produce an expandable stethoscope with software transfer capability, yet we so no such product in the marketplace.

The Bredesen patent, and subsequent reduction to practice in the marketplace, comprises a device that facilitates the transfer of heart sounds i.e. medical measurements from the stethoscope to a plotter or an external storage device for archiving. It is commonplace to plot medical waveforms, it is commonplace to save medical records for archiving. Yet this is procedurally and conceptually entirely different from expanding the functions of a stethoscope through the downloading of new software. One skilled in the art, using common sense, would not be expected to make the leap from plotting a waveform to inventing a software-upgradeable medical device. There are simply too many inventive steps, and the invention can only be reconstructed from the prior art using hindsight. Given that those skilled in the art have not demonstrated such hindsight in the marketplace is further evidence that the inventive steps are too substantial to be obvious.

In another aspect of KSR, the Court's argues that that the "background knowledge possessed by a person having ordinary skill" should be considered. Medical devices, including stethoscopes, are regulated in the United States by the US Food and Drug Administration (FDA). A device is approved by the FDA with a given, fixed, software configuration. Modifying the software constitutes a design change that may require further FDA approval. The testing procedures for any given software version are arduous and specific to that version of software. Applying "common sense", those practicing the art work towards one approved, thoroughly tested version of software for a medical device, and are loathe to make further changes. The concept of facilitating software changes through a communications means on the device, thereby changing its features easily flies in the face of "common sense" to those practicing the art of medical device invention. It is entirely non-obvious that a medical device, and a stethoscope in particular, can ort should be provided with this level of software flexibility with an expectation of a successful result.

Another feature claimed in the present invention that as yet does not exist in the marketplace is the feature to "**expand the functions**" of a stethoscope. The specification further discloses numerous expanded functions that can be added to a stethoscope beyond the basic one of listening to a patient. Once again, the "marketplace" test in KSR suggests the non-obviousness of the present invention. Not only, as stated above, is there no stethoscope that can be expanded via software, there is currently no stethoscope in the marketplace that has any method whatsoever of expanding the functions of a stethoscope beyond listening to patients.

One must inevitably conclude that 16 years after Bredesen, 9 years after the priority date of the present invention, those with ordinary skill, inventing new stethoscopes, have yet to produce the claimed invention or even limited features of the claimed invention despite the fact that all major companies in this field released new products during this time period. Were this obvious in light of the prior art, or obvious if one applied knowledge and common

sense and even hindsight, we would expect marketplace activity to have produced the present invention.

The above arguments are further consistent with the tests applied under Graham. It is clear that if one considers (a) prior art as cited by Examiner (b) differences between prior art and the claimed invention as discussed above and in previous communications with Examiner, (c) the level of ordinary skill (even when considered with some hindsight) and (d) evaluating evidence of secondary consideration (as discussed above in light of KSR); one must conclude that the claimed invention passes the Graham test.

Therefore, under present patent examination guidelines under Graham and KSR, Claim 19 and its dependent claims are clearly allowable.